

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION)	
_____)	MDL NO. 1203
THIS DOCUMENT RELATES TO:)	
SHEILA BROWN, et al.)	
v.)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8547

Bartle, C.J.

September 30, 2010

Brenda Bolding ("Ms. Bolding" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In September, 2002 claimant submitted a completed Green Form to the Trust signed by her attesting physician, Stephen Raskin, M.D., F.A.C.C. Dr. Raskin is no stranger to this litigation. According to the Trust, Dr. Raskin has signed in excess of 82 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated March 9, 2002, Dr. Raskin attested in Part II of Ms. Bolding's Green Form that she suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of

2. (...continued)

describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

50% to 60%.³ Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$628,632.⁴

In the report of claimant's echocardiogram, the reviewing cardiologist, Donald Trillos, M.D., F.A.C.C., stated that claimant had "[m]oderate mitral regurgitation with a RJA/LAA of 35%." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. In addition, Dr. Trillos noted that claimant's left atrium was "[n]ormal in size," and measured the left atrial dimension as 4.3 cm in the apical four chamber view and 3.3 cm in the parasternal long axis view. The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See id. § IV.B.2.c.(2)(b)ii). Dr. Trillos also found that Ms. Bolding had an ejection fraction

3. Dr. Raskin also attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition, however, is not at issue in this claim.

4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). An abnormal left atrial dimension and a reduced ejection fraction are each one of the complicating factors needed to qualify for a Level II claim.

of 55% to 59%. An ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. See id. § IV.B.2.c.(2)(b)iv).

In July, 2005, the Trust forwarded the claim for review by Keith B. Churchwell, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Churchwell concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation because claimant's echocardiogram demonstrated only mild mitral regurgitation. In support of this conclusion, Dr. Churchwell explained that there was "[o]verestimation of the jet size by [the] technologist by the planimetry seen on the tape" Dr. Churchwell also concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had an abnormal left atrial dimension. Dr. Churchwell measured claimant's left atrial dimension as 4.3 cm in the apical four chamber view and 3.1 cm in the parasternal long axis view. Finally Dr. Churchwell determined that there was no reasonable medical basis for Dr. Raskin's finding of a reduced ejection fraction, noting that there was "[e]xcellent [left ventricular] systolic function, [ejection fraction]>60% with normal wall motion present."

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination denying Ms. Bolding's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this

adverse determination.⁵ In contest, claimant submitted a letter from Dr. Trillos, who re-reviewed claimant's echocardiogram and opined that claimant had moderate mitral regurgitation "within the 20% to 40% range." Claimant argued, therefore, that there was a reasonable medical basis for her attesting physician's finding of moderate mitral regurgitation.⁶

The Trust then issued a final post-audit determination, again denying Ms. Bolding's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for an issuance of an Order to show cause why Ms. Bolding's claim should be paid. On February 13, 2006 we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5986 (Feb. 13, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special

5. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Bolding's claim.

6. In her contest, claimant did not address the auditing cardiologist's findings of a normal left atrial dimension and a normal ejection fraction.

Master. The Trust submitted a reply on May 2, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁷ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's findings that she had moderate mitral regurgitation and either an abnormal left atrial dimension or a reduced ejection fraction. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form that are at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a

7. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

reasonable medical basis for the answers, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Bolding reasserts the arguments that she made in contest; namely, that there is a reasonable medical basis for her claim because her attesting physician's finding of moderate mitral regurgitation is supported by the finding of Dr. Trillos. Claimant also contends that her Green Form and corresponding echocardiogram report provide adequate support for Dr. Raskin's finding that she had an abnormal left atrial dimension and a reduced ejection fraction.

In response, the Trust asserts that claimant has not established a reasonable medical basis for her claim because she "failed to address or rebut the specific findings of Dr. Churchwell." The Trust also notes that claimant merely restates the findings of her attesting physician, Dr. Raskin, and the cardiologist that prepared her echocardiogram report, Dr. Trillos. The Trust further notes that the letter from Dr. Trillos did not address the auditing cardiologist's findings of a normal left atrial dimension and a normal ejection fraction.

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Specifically, Dr. Abramson stated, in relevant part, that:

In reviewing the transthoracic echocardiogram, my visual estimate is that there is only mild mitral regurgitation. I chose not to measure the jet because it is not even close to being moderate. Most of the cardiac cycles contain no mitral regurgitation.... [I]n the apical-long-axis view the technologist measures a regurgitant jet area of 1.35 cm² which is a very small jet. The technologist did trace the mitral regurgitant jet in the parasternal long axis (which is the largest mitral regurgitant jet in the entire study, and not representative of the other cardiac cycles) and tried to compare it to a tracing of the left atrium in this parasternal long axis view. This is not accurate because you would always obtain a falsely small left atrial area from the parasternal view.... Even considering this one larger jet in the parasternal long axis, there is still only mild mitral regurgitation by visual estimation.

Dr. Abramson also found no reasonable medical basis for the attesting physician's finding of an abnormal left atrial dimension. Dr. Abramson measured claimant's left atrial dimension as 4.5 cm in the apical four chamber view and 3.3 cm in the parasternal long axis view. Finally, Dr. Abramson determined that there was no reasonable medical basis for finding a reduced ejection fraction because claimant's ejection fraction was ">65% and within normal limits."

In response to the Technical Advisor Report, claimant argues that the Technical Advisor's assessment of her echocardiogram should be disregarded because the "findings are inconsistent with Dr. Trujillo's (sic) finding and fail to account for very significant symptomology."

After reviewing the entire Show Cause Record, we find that claimant does not adequately challenge the findings of the auditing cardiologist and the Technical Advisor that there is no reasonable medical basis for Dr. Raskin's representation that Ms. Bolding had moderate mitral regurgitation. Despite the opportunity in contest to present additional evidence in support of her claim, Ms. Bolding rests only on Dr. Raskin's check-the-box diagnosis on her Green Form and the letter of Dr. Trillos. Neither claimant nor her cardiologists refute or respond to Dr. Churchwell's determinations that there was "[o]verestimation of the jet size by [the] technologist" and that only "mild [mitral regurgitation] is present." Ms. Bolding also does not refute Dr. Abramson's findings that "[m]ost of the cardiac cycles contain no mitral regurgitation" and that there is "only mild mitral regurgitation by visual estimation."

Similarly, claimant does not adequately challenge the findings of Dr. Churchwell and Dr. Abramson that there is no reasonable medical basis for the attesting physician's representation that claimant had an abnormal left atrial dimension and a reduced ejection fraction. Specifically, Dr. Churchwell concluded that claimant's "[left atrium] measures within the normal range in both dimensions" and that claimant had "[e]xcellent [left ventricular] systolic function, [ejection fraction]>60% with normal wall motion present." Dr. Abramson also observed that claimant's left atrial dimension was normal and that claimant's ejection fraction was ">65% and within normal

limits." Again, however, Ms. Bolding rests only on Dr. Raskin's check-the-box diagnosis on her Green Form and the letter of Dr. Trillos.⁸ Mere disagreement with the auditing cardiologist and the Technical Advisor is insufficient to meet a claimant's burden of proof.⁹

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation and either an abnormal left atrial dimension or a reduced ejection fraction. Therefore, we will affirm the Trust's denial of Ms. Bolding's claim for Matrix Benefits.

8. Notably, Ms. Bolding did not explain the normal left atrial dimension reported by Dr. Trillos.

9. Given our disposition, we need not address the Trust's remaining arguments.